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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,379	05/11/2001	Paul M. Lizardi	25006.0005U3	7125

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EXAMINER

LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/853,379

Applicant(s)

LIZARDI, PAUL M.

Examiner

Frank W Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-45, 53, 57, 58, 62-66 and 69-172 is/are pending in the application.
- 4a) Of the above claim(s) 70-161 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 42-45, 53, 57, 58, 62-66, 69 and 162-172 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Non-compliant Amendment

1. Applicant's response to Non-compliant Amendment filed on December 8, 2003 has been entered and now applicant's amendment has accepted by the office.

Election/Restrictions

2. Applicant's election with traverse of Group I, claims 42-45 and 162-171 on October 20, 2003 is acknowledged. The traversal is on the ground(s) that: (1) Groups I, II, and III should be examine together because: (i) "the remaining claims of Group II, claims 53, 57, 58 and 61, now depend from claim 42 and are thus directed to the same core invention, that being a method of amplifying nucleic acids using rolling circle amplification. The claims in Groups I and II are based on common steps (steps (a) through (d)). Step (e) now appears only in dependent claims and reflects different embodiments of the core method."; (ii) "[A]pplicant respectfully submits that performing different searches for groups of claims, especially those classified in the same class, does not constitute a serious burden to the Examiner. While the Applicant agrees that a different search might have been needed on the two groups of claims, the searches would not have been limitless or without boundaries that can be easily identified. It is respectfully noted that many patents have issued containing method claims comprising different steps, and applicant respectfully asserts that the difference in step (e) of the claims within Groups I and II are not separate components of the invention that require their own search, but rather are embodiments that should be searched in addition to that of the base method."; (iii) "the remaining claims of Group III, claims 62-66 and 69, now depend from claim 42 and are

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withdrawn to the same method as the claims of Groups I and II. Regarding step (c), applicant respectfully submits that step (c) reflects a specific embodiment of the base method.”; (2) “rejoinder and examination of claims 70-77 with claims 42-45 and 162-171, claims 53, 57 and 58, claims 62-66 and 69, and claims 78-161 is respectfully requested.” because “the products in Claims IV and V are used in the same process in the methods of Group I as they are in the methods of Group II, Group III and Group VI. As amended, the claims in Groups IV and V recite that the kit is for use in rolling circle amplification, thus, it is respectfully asserted that the products are used for the same process in the methods of each of the groups.”; (3) “rejoinder and examination of claims 42-45 and 162-171, and claims 78-161 is respectfully requested.” because “[T]he search for such embodiments within the method of Group I would be co-extensive with any search for the method of Group VI. The result is that there would be no significant additional search required in examining both groups of claims. Further, applicant respectfully submits that performing different searches for groups of claims, especially those classified in the same class, does not constitute a serious burden to the Examiner. The search required, even if different in some particular, is not limitless or without boundaries that can be easily identified. It is respectfully noted that many patents have issued containing method claims comprising different steps, and applicant respectfully asserts that the presence in step (e) of the claims with in Group I is not a separate component of the invention that requires its own search, but rather is an embodiment that should be searched in addition to that of base method.”; (4) “rejoinder and examination of claims 53 and 57 and claims 78-161 is respectfully requested.” because “[T]he search for such embodiments within the method of Group II would be co-extensive with any search for the method of Group VI. The result is that there would be no significant additional

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search required in examining both groups of claims. Further, applicant respectfully submits that performing different searches for groups of claims, especially those classified in the same class, does not constitute a serious burden to the Examiner. The search required, even if different in some particular, is not limitless or without boundaries that can be easily identified. It is respectfully noted that many patents have issued containing method claims comprising different steps, and applicant respectfully asserts that the presence in step (e) of the claims with in Group I is not a separate component of the invention that requires its own search, but rather is an embodiment that should be searched in addition to that of the base method.”; and (5) “rejoinder and examination of claims 70-72 and 74-76 and claims 73 and 77 is respectfully requested.” because “[F]irst, Applicant respectfully submits that the claims in Groups IV and V are directed to the same core invention, that being a linear vector for amplifying nucleic acids using rolling circle amplification. Second, applicant respectfully submits that performing different searches for groups of claims, especially those classified in the same class, does not constitute a serious burden to the Examiner. While there are some differences in the two groups of claims, these differences are no more than is commonly found in dependent claims drawn to the same invention. This does not constitute a sufficient burden to support the present restriction requirement.”.

Since applicant’s arguments (see above) on previous restriction Groups I, II, and III are based on the amended claims 42, 53, 57, 62, 65, 66, and 69, claims 54-56, 59-61, 67, and 68 have been canceled, a new claim 172 is added, the arguments on claims 42-45, 53-69, and 162-171 are moot. After carefully considered applicant’s arguments, the examiner agrees to combine claims 42-45, 53, 55, 57, 58, 62-66, 69, and 162-172 together. However, claims 42-45, 53, 57,

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58, 62-66, 69, and 162-172 are required to be further species election (see below) and the arguments on restriction Groups IV, V, and VI have not been found persuasive toward the withdrawal of the restriction requirement nor persuasive toward the relaxation of same such that Groups I to VI will be examined together. First, the restriction was not based on the classification. Second, Claims 42-45, 53, 57, 58, 62-66, 69, and 162-172 (Groups I, II, and III) and claims 78-161 (Group VI) are considered to be different invention because they require different searches. For example, a search for step (e) of claim 162, which is required for Group I, is not required for Group VI while a search for a vector wherein the second strand of the vector can not be coupled recited in claim 78, which is required for Group VI, is not required for Groups I, II, and III. Thus, there is a burden to search Groups I, II, III, and VI together. Third, although Groups IV and V may be used in the same process and are classified to the same class, the searches for Groups IV and V are not coextensive. For example, a search for the vector recited in claim 70, which is required for Group IV, is not required for Group V while a search for the vector recited in claim 73, which is required for Group V, is not required for Group IV. Thus, there is a burden to search Groups IV and V together. Fourth, since Groups I, II, III, and VI are directed to methods while claims IV and V are directed to products, the search for method groups and product groups are different. For example, a search for step (c) of claim 42, which is required for Group I, is not required for Groups IV and V while a search for a kit, which is required for Groups IV and V are not required for Groups I, II, III, and VI. Therefore, the requirement for Groups IV, V, and VI is still deemed proper and is therefore made FINAL.

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3. After reviewed amended claims 42, 53, 57, 62, 65, 66, and 69, the examiner considers that claims 42-45, 53, 57, 58, 62-66, 69, and 162-172 (previous restriction Groups I, II, and III) contain claims directed to the following patentably distinct species of the claimed invention:

(1) species with a method step for screening the identified nucleic acid molecules of interest by coupled transcription-translation to identify nucleic acid molecules encoding protein molecules with a specific catalytic activity (claim 53)

(2) species with a method step for subjecting the identified nucleic acid molecules of interest to coupled transcription-translation to produce transcripts and proteins (claims 57 and 162-172)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are claims 42-45, 58, 62-66, and 69.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

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be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Claims 42-45, 53, 57, 58, 62-66, 69, and 162-172 (previous restriction Groups I, II, and III) further contain claims directed to the following patentably distinct species of the claimed invention:

(3) the method of claim 42 are amplified by a method recited in claims 62 and 66 (claims 62 and 66)

(4) the method of claim 42 are amplified by a method recited in claims 65 and 69 (claims 65 and 69)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are claims 42-45, 53, 57, 58, 63, 64, and 162-172.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.


5. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
March 19, 2004


FRANK LU
PATENT EXAMINER